REMARKS

Claims 1 and 3 to 45 are pending. Claims 1 and 3 to 20 are currently under consideration and claim 2 was previously canceled. Claims 21 to 45 are withdrawn. Claims 1, 3 and 13 to 20 are currently amended.

Claim Amendments

Claim 1 has been amended to delete reference to the wound or graft dressing that was added in the amendment filed November 15, 2010.

Claim 13 has been amended to depend directly from claim 1 and is clarified to specify that the desired thickness is that of a wound or graft dressing and that the resulting polymer forms the wound or graft dressing. Support for this amendment is found at least at paragraphs [0010], [0032], [0051], [0053] and [0063] to [0082] of the application as originally filed. The claim has also been amended to delete the phrase "the step of".

The claim dependencies of claims 3 and 14 to 20 have been amended for consistency with the amendment to the claim dependency of claim 13.

It is believed no new matter has been added by these amendments.

Comments in Response to Office Action

The Examiner commented that the amendment to independent claim 1 as filed November 15, 2010, to recite that the process prepared a wound or graft dressing that comprises the thermosensitive nanoporous polymer resulted in the claims no longer falling within the elected invention directed to a process for preparing a thermosensitive nanoporous polymer. Claim 1 is currently amended as indicated above, and thus once again specifies that the process is for

preparing a thermosensitive nanoporous polymer. The remaining clarifying amendments made to claim 1 in the amendment filed November 15, 2010 have been retained.

In addition to the amendment to claim 1, claim 13 is currently amended in order to clarify that the forming the microemulsion into a desired thickness prior to polymerization (as previously specified in the claim) results in a wound or graft dressing, as described at least in paragraphs [0032] and [0051] of the application as originally filed. Claim 13 now depends directly from claim 1 and the remaining dependent claims have been amended to reflect this alteration in dependency of claim 13; claims 3 to 12 and 14 to 20 now depend directly or indirectly from claim 13, thus incorporating this feature of preparing the microemulsion into the form of a wound or graft dressing.

Claim 1 as currently amended is directed to a process for forming a thermosensitive nanoporous polymer, as specified in the elected invention group. Claim 13 was originally included in the elected invention group, and thus the invention group included pre-forming of the microemulsion prior to polymerization. As indicated in paragraph of [0051] of the application, pre-forming to a desired thickness results in a membrane, which membrane is useful as a wound or graft dressing, as indicated in paragraphs [0032], [0053], [0063], [0065] and [0077] of the application. Thus, this amendment to claim 13 clarifies an existing feature that was found in the elected claim group, and thus the claims as currently amended fall within the elected invention group.

The remaining remarks reflect the remarks as filed November 15, 2010, with the exception that the arguments have been amended for consistency with the current claim amendments, where appropriate.

35 USC 112 Rejections

The Examiner rejected claims 1 and 3 to 20 under 35 USC 112, second paragraph, as indefinite due to inclusion of the term "discontinuous swelling ratio". The Examiner indicated that the claim does not define or state what is compared for determining the ratio.

The current claims are definite, for at least the following reasons.

The term "swelling ratio" is a term commonly used and understood in the art, as evidenced by the use of this term in many of the cited references. Upon reading the claims, a skilled person will appreciate that the swelling ratio is a comparison of a given property (e.g. volume or weight) for the gel when in an unswelled state and a fully swelled state. Furthermore, upon reading the claim, it will be apparent what a discontinuous swelling ratio is, namely one having a discontinuity such as an interruption or break when expressed as a function of a variable parameter. It will also be apparent that such a discontinuity occurs in the vicinity of the lower critical solution temperature when the swelling ratio is expressed as a function of temperature.

Accordingly, Applicants submit that upon reading claim 1 as currently presented (and claims 3 to 20, each of which depend directly or indirectly from claim 1), a skilled person will appreciate the meaning of the phrase "discontinuous swelling ratio around a lower critical solution temperature", and will not consider the claim indefinite.

Applicants respectfully request withdrawal of this rejection under 35 USC 112, second paragraph.

35 USC 103 Rejections

(i) Gan et al. and Vakkalanka et al.

The Examiner maintained the rejection of claims 1 and 3 to 13 under 35 USC 103 as being unpatentable over the combination of cited references Gan et al. in view of Vakkalanka et al.

Applicants respectfully submit that these claims are patentable over the cited references, for at least the following reasons.

Independent claim 1 as currently amended is directed to a process for preparing a thermosensitive nanoporous random polymer, the process comprising polymerizing a microemulsion comprising a first monomer that is capable of forming a thermosensitive polymer and a polymerizable surfactant, wherein the resulting polymer exhibits a discontinuous swelling ratio around a lower critical solution temperature.

A skilled person would have no reason to combine Vakkalanka et al. and Gan et al., and would have no reason to expect that combination of the methods described in these references would be successful.

Vakkalanka et al. indicates that larger mesh size (i.e. pore size) is desirable. Specifically, the reference indicates that swelling results in increased mesh size, allowing water to diffuse in and drug to diffuse out (which is a desired result), and that upon environmental change (e.g. pH or temperature), the hydrogel decreases mesh size, thereby limiting drug release from the system (see page 221, second paragraph of Introduction of Vakkalanka et al.).

Gan et al. indicates that when polymers are formed from a microemulsion with a polymerizable surfactant, the resulting polymer has pore sizes of nanometer range (see page 5339, Introduction of Gan et al.).

A polymer having nanometer sized pores has smaller pore size than a polymer prepared by conventional polymerization techniques as in Vakkalanka et al. Thus, based on the combined descriptions of Vakkalanka et al. and Gan et al., a skilled person would not be directed to combine the nanometer pore size and the added inclusion of the surfactant of Gan et al. in the polymer with the thermosensitive monomer of Vakkalanka et al. More particularly, a skilled person would not be directed to use a random polymer with nanopores when Vakkalanka et al. uses a block polymer with blocks of thermosensitive polymer. Vakkalanka et al. indicates that a random copolymer exhibits decreased swelling as compared with a block copolymer, implying that the random copolymer even when swelled thus has smaller pore sizes, which is less desirable according to Vakkalanka et al. (see final paragraph of Vakkalanka et al., on page 225).

The Examiner has indicated that although there is no evidence provided, the polymers described by Vakkalanka et al. likely exhibit a discontinuous swelling ratio around the lowest critical solution temperature. The Examiner basis this opinion on the description provided in the present application and also pointed to Figures 1 and 2 of Vakkalanka et al. This approach by the Examiner is not proper, given that the polymers described in Vakkalanka et al. are not the same as the presently claimed polymers. The present polymers are nanoporous as a result of being formed from a microemulsion that contains a polymerizable surfactant. In contrast, the Vakkalanka et al. polymers are not nanoporous and do not contain a polymerizable surfactant. Figures 1 and 2 of Vakkalanka et al. are not comparable to Figure 3 of the present application, as the swelling ratio in the Figures of Vakkalanka et al. is not expressed as function of temperature. Rather, the swelling ratio is described as a function of time as either pH or temperature is cycled over time.

Furthermore, the Examiner has pointed to paragraph [0097] of the present application as stating that the only requirement to demonstrate a discontinuous swelling ratio around an LCST is inclusion of NIPAAm. Paragraph [0097] of the present application does not make such a statement. Paragraph [0097] of the application indicates that the membranes produced by the methods described in the present application exhibited a discontinuous temperature-dependent swelling ratio and that "the swelling behaviour is likely affected by the LSCT of PNIPAAm." Also, the paragraph indicates that "In general, an increased NIPAAm monomer content in the microemulsion improved the sensitivity of the membranes to temperature." (Emphasis added.) Thus, paragraph [0097] is clearly referring to membranes (and polymers) produced by the methods of the present application, not all polymers or all membranes containing a monomer that forms a thermosensitive polymer. Thus, there is no evidence to support the Examiner's contention that the polymers described by Vakkalanka et al., which are physically and chemically different from the presently claimed polymers, would have the same physical and chemical properties based on the description of the presently claimed polymers in the instant application.

Furthermore, claim 13 has been currently amended to indicate that the microemulsion is pre-formed into a desired thickness of a wound or graft dressing and that upon polymerization, the resulting polymer forms the wound or graft dressing. Thus, in addition to the above arguments for independent claim 1, currently amended claim 13 has been clarified to expressly state that in the claimed method, the polymer is prepared as a wound or graft dressing. As well, claims 3 to 12 are amended to depend from currently amended claim 13 and thus claims 3 to 13 incorporate the feature of preparing a wound or graft dressing. As indicated by the Examiner, neither Gan et al. nor Vakkalanka et al. relate to wound or graft dressings, and thus do not disclose all of the features of the present claims. These cited references also do not describe or suggest that the described polymers are used as wound or graft dressings. A skilled person would not combine these references or expect combination of these references to result in the presently claimed method of producing a wound or graft dressing.

The Allen et al. reference referred to in the previously filed response (a copy of which was filed with an Information Disclosure Statement on November 15, 2010) indicates that modifications with respect to the physiochemical properties of soft amorphous materials can lead to significant impacts on the interaction of cells with the material (see final paragraph of Allen et al., page 6336). As stated above, in the presently claimed processes, the polymer is nanoporous and also includes a surfactant as one of the monomers in the polymer. Thus, the polymers resulting from the currently claimed methods have different physical and chemical properties from those described by Vakkalanka et al. Thus, Allen et al. would further underscore to a skilled person that Vakkalanka et al. should not be combined with Gan et al., and that any such combination would not reasonably be expected to provide a wound or graft dressing as claimed by the currently claimed processes.

As well, Allen et al. indicates that increasing concentrations of NIPAAm increases the hydrophilicity of the resulting polymers and was less desirable in terms of interaction of cells with the polymer (see paragraph bridging pages 6333 and 6334 of the Allen et al. reference).

The Examiner indicated that Allen et al. is not relevant in the present context as the claims did not specify a method of using the polymer as a wound dressing nor do the Gan et al. and Vakkalanka et al. methods refer to wound dressings. Claims 3 to 13 as currently amended specify a process of producing a wound or graft dressing, in keeping with the description of the originally filed application. A wound or graft dressing, once applied to a wound or graft, necessarily interacts with living tissue that includes living cells. Thus, Allen et al. is relevant to a discussion of the combination of Gan et al. and Vakkalanka et al. and the presently claimed processes.

Accordingly, Applicants submit that the combination of Gan et al. and Vakkalanka et al. do not render obvious claim 1 as currently amended and claims 3 to 13 which depend from claim 1 and request withdrawal of this rejection.

(ii) Gan et al., Vakkalanka et al. and Liu et al.

The Examiner maintained the rejection of claims 14 to 20 under 35 USC 103 as being unpatentable over the combination of cited references Gan et al. and Vakkalanka et al. and further in view of Liu et al.

Applicants respectfully submit that these claims are patentable over the cited references, for at least the following reasons.

Claims 14 to 20 each depend indirectly from claim 13 and incorporate all of the features of independent claim 1 and dependent claim 13. As stated previously, and in light of the above arguments, Liu et al. does not compensate for the defect in the combination of the Gan et al. reference and Vakkalanka et al. reference.

As stated previously, in *In re Peterson*, the court held that each of the three cited references Shah, Wukusick and Bieber disclosed ranges of all the claimed elements that overlapped the claimed ranges, not that one of the references disclosed ranges of some of the elements. Here, the Examiner points only to Gan et al. as disclosing overlapping ranges, while stating that Gan et al. does not disclose all of the claimed elements. Thus, Applicants submit that Gan et al. cannot disclose ranges of elements that overlap with the currently claimed ranges given that Gan et al. does not disclose any range of a monomer that forms a thermosensitive polymer. The Examiner has further indicated that Vakkalanka et al. and Liu et al. do not disclose overlapping ranges, and thus Applicants submit that the references thus cannot be cited in a rejection that follows *In re Peterson*. Thus, none of Gan et al., Vakkalanka et al., or Liu et al.

describe each of the claimed elements (let alone ranges for each element), as acknowledged by the Examiner.

As previously stated in the previous response, even where a given reference discloses some of the elements of each of claims 14 to 20, the ranges for certain elements between the three references are not consistent with each other.

Thus, Applicants submit that a skilled person, having regard to Gan et al., Vakkalanka et al., and Liu et al., would not arrive at the specific components and concentrations of claims 14 to 20.

Thus, in addition to the comments provided above for the combination of Gan et al. and Vakkalanka et al., Applicants submit that further combination with the Liu et al. reference does not render the presently claimed processes of claims 14 to 20 as obvious.

(iii) Gan et al. and Lee et al.

The Examiner maintained the rejection of claims 1 and 3 to 13 under 35 USC 103 as being unpatentable over the combination of cited references Gan et al. in view of Lee et al.

Applicants respectfully submit that claims 1 and 3 to 13 are patentable over the cited Gan et al. and Lee et al. references, for at least the following reasons.

As stated in the previously filed response, independent claim 1 specifies that the resulting polymer exhibits a discontinuous swelling ratio around the LCST. The Examiner was not persuaded that this feature distinguishes over Gan et al. in combination with Lee et al., on the basis that any polymer containing NIPAAm must necessarily possess this feature, based on the description of the present application.

As stated above, reference to the present application is not relevant to the polymers of Lee et al., as the polymers resulting from the presently claimed processes have different physical and chemical properties, namely having nanometer sized pores and including a surfactant as one of the polymerized monomers in the resulting polymer. As indicated above, paragraph [0097] of the present application indicates that the membranes produced by the methods described in the present application (i.e. the statement does not apply to all thermosensitive membranes or polymers at large) exhibited a discontinuous temperature-dependent swelling ratio.

The Examiner points to figure 3 of Lee et al. as demonstrating a discontinuous swelling ratio around the LCST of the polymer. Lee et al. does not indicate what the LCST is for the polymers, and in any event the lines in Figure 3 do not demonstrate an interruption or discontinuity. It is not clear from Figure 3, and nor does the Lee et al. reference otherwise indicate, that any imperfections in the graphs of Figure 3 are not merely data fluctuations, given that the data points before and after any apparent imperfections appear to fall on the same line.

As indicated above, dependent claim 13 as currently amended specifies that the method produces a wound or graft dressing. Neither Gan et al. nor Lee et al. relate to wound or graft dressings, and thus do not disclose all of the features of present claims 3 to 13. These cited references also do not describe or suggest that the described polymers are used as wound or graft dressings. As well, a skilled person would not combine the Gan et al. and Lee et al. references or expect combination of these references to result in the presently claimed method of producing a wound or graft dressing, particularly in light of the Allen et al. reference and the indication that change in physical or chemical properties of a soft amorphous material can impact the manner in which cells interact with the material.

The comments made above relating to the Allen et al. reference under the rejection based on Gan et al. and Vakkalanka et al. are equally applicable here. Lee et al. indicates that drug release decreases with decreasing NIPAAm as a result of less swelling, indicating that reduced

pore size is less favorable for the purposes of Lee et al. (see second column on page 230 of Lee et al.). The greater the volume change, the greater the drug release. Combination with Gan et al. to include nanoporosity and to include a surfactant as polymerizable monomer would change the physical and chemical properties and affect the interaction of the polymer with cells. Thus, in light of the Allen et al. reference described above, it would not be apparent to a skilled person to combine a polymerizable surfactant in a microemulsion together with a monomer capable of forming a thermosensitive polymer to yield a nanoporous wound or graft dressing, as claimed in current claim 13.

In light of the description of Lee et al. relating to a combination of thermosensitivity and pH sensitivity, the absence of any description relating to a discontinuous swelling ratio around a lower critical solution temperature, and in light of the Allen et al. reference, Applicants submit that the presently amended claims are patentable over the combination of the Gan et al. reference and the Lee et al. reference.

Thus, claim 1, claim 13 and claims 3 to 12 which depend from claim 13, are patentable over the cited combination of references Gan et al. in view of Lee et al.

(iv) Gan et al., Lee et al., and Liu et al.

The Examiner maintained the rejection of claims 14 to 20 under 35 USC 103 as being unpatentable over the combination of cited references Gan et al. and Lee et al. and further in view of Liu et al.

Applicants respectfully submit that these claims are patentable over the cited references, for at least the following reasons.

Claims 14 to 20 each depend indirectly from claim 13 and incorporate all of the features of independent claim 1 and dependent claim 13. As stated previously, and in light of the above

arguments, Liu et al. does not compensate for the defect in the combination of the Gan et al. reference and Lee et al. reference.

As stated above, Applicants submit that the *In re Peterson* case does not apply to the present application, for the reasons stated above.

As with the previous combination, the ranges given in the Lee et al. reference are not consistent with the Gan et al. reference and the Liu et al. reference, and the Lee et al. reference stands in contrast to the Vakkalanka et al. reference cited above.

Thus, Applicants submit that a skilled person, having regard to Gan et al., Lee et al., and Liu et al., would not arrive at the specific components and concentrations of claims 14 to 20, particularly given the discrepancies between the three cited references, given the discrepancies between the Lee et al. reference and the Vakkalanka et al. reference, given the fact that none of the cited references discloses ranges for each element within claims 14 to 20, given that the one reference that does include NIPAAm (Lee et al.) also includes acrylamide (which imparts pH sensitivity) and ethanol, and given the disclosure of Allen et al. which indicates that even keeping bulk properties essentially unchanged, changes in surface properties can have a significant effect on the polymer properties and effect. Thus, Applicants submit is not a matter of simply selecting the amount of each component from a range within a single reference as was the case in *In re Peterson.*

Thus, in addition to the comments provided above for the combination of Gan et al. and Lee et al., Applicants submit that further combination of the Liu et al. reference does not render the presently claimed processes of claims 14 to 20 as obvious.

Summary

In summary, based on all of the above arguments, Applicants submit that the Examiner has failed to set out a prima facie case of obviousness. The rejections directed to independent claim 1, either based on Gan et al. in combination with Vakkalanka et al. or on Gan et al. in combination of Lee et al., are not tenable because the cited references do not disclose all of the features of the independent claim.

In addition, dependent claim 13 depends from claim 1 and includes the further feature of pre-forming the microemulsion so as to result in a polymerized wound or graft dressing. The remaining claims 3 to 12 and 14 to 20 depend from claim 13 and thus include this feature of forming a wound or graft dressing.

There is no reason for a skilled person to combine the cited references to arrive at the presently claimed processes and no reason that a skilled person would reasonably expect combination of the cited references to result in a wound or graft dressing.

Thus, claims 1 and 3 to 20 are patentable over each of the combinations of cited references. Applicants respectfully request withdrawal of the rejections under 35 USC 103.

Information Disclosure Statement

Applicants respectfully request that the Examiner consider the contents of the information disclosure statement filed November 15, 2010.

One of the documents submitted with the information disclosure statement filed November 15, 2010, is an Office action issued in corresponding People's Republic of China Application No. 200480020822.0. The relevance of this document will be apparent from an English-language translation submitted with the information disclosure statement filed November 15, 2010.

Applicants also respectfully request that the Examiner consider the contents of the information disclosure statement filed June 10, 2009.

The Examiner commented that the information disclosure statement filed June 10, 2009 is non-compliant due to either a missing statement under 37 CFR 1.97(e) or a missing fee.

Applicants point out that the information disclosure statement filed June 10, 2009 included a deposit account charge authorization to satisfy the fee requirement.

Also, the information disclosure statements filed June 10, 2009 and November 15, 2010, were filed before the mailing of a first Office action after the filing of a request for continued examination. (An RCE was filed on November 15, 2010). As a result, pursuant to 37 CFR 1.97(b)(4), neither a statement under 37 CFR 1.97(e) nor a fee should be required to obtain consideration of the information disclosure statements at this time.

However, if the Patent Office determines that a fee is required to obtain consideration of the information disclosure statement filed June 10, 2009, please charge any such fee, or credit overpayment, to Deposit Account No. 02-4550.

Conclusion

Applicants respectfully request entry of this amendment, favorable consideration and withdrawal of the rejections.

Respectfully submitted,

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